UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/868,293	03/04/2002	Giulio Ratti	PP01641.102	8906

7590 12/11/2003

Dale H. Hoscheit
Banner & witcoff, LTD.,
1001 G Street N.W.
Washington, DC 20001-4579

EXAMINER	
BASKAR, PADMAVATHI	

ART UNIT	PAPER NUMBER
1645	16

DATE MAILED: 12/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/868,293	Applicant(s) RATTI, GIULIO	
	Examiner Padmavathi v Baskar	Art Unit 1645	

-- The MAILING DATE of this communication appears on th cover sheet with th correspondenc address --

P ri d f r Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 September 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *25-48* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *25-48* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Applicant's amendment filed on 9/22/03 paper # 10 is acknowledged. Claims 1 –24 have been canceled. Claims 25 - 48 have been added. Claims 25 - 48 are pending in the application.

Priority

2. This application is a national stage entry of is a national stage entry of PCT/IB99/02065 International Filing Date: 12/17/1999, which claims priority to U.K 9828000.1, 12/18/1998.

Information Disclosure Statement

3. Information Disclosure Statement is not filed in this application.

Drawings

4. The drawings are objected to by the draftsperson under 37 C.F.R. 1.84 or 1.152. See attached PTO-948 for details.

Specification - Informalities

5. Claims should begin with "I claim" or "'We claim" or "What is claimed is".

The specification on page 2 refers to proteins 5-11 and 13-55 in Table II. However, page 3, refers to proteins 5-55 in Table II. Therefore, it is unclear which one is correct. It appears that this discrepancy is due to a typographical error. However, Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Election/Restriction

6. Applicant's election of Group II, Claims 1-4, 12-15 and 18, drawn to composition and a method of treatment using said composition, with respect to protein L7/L12, spot number 12, with traverse in Paper No. 15 is acknowledged. Since no arguments put forth to support traversel, the requirement is still deemed proper and is therefore made FINAL.

7. Claims 1-24 have been canceled and new claims 25-48 have been added. The newly amended claims read on the elected invention and therefore, claims 25-48 are under examination as an elected invention. Applicant timely traversed the restriction (election) requirement in Paper No. 15.

Claim Rejections - 35 U.S. C. 112, first paragraph

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 25-48 are rejected under 35 U.5.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant is referred to the interim guidelines on written description published June 15, 1998 in the Federal Register at Volume 63, Number 114, pp 32639-32645 (also available at www.uspto.gov). This is a written description rejection.

The specification describes and identifies *Chlamydia trachomatis* protein L7/L12 from L2 strain. The invention also provides predicted pI and molecular weight of L7/L12 *C.trachomatis* as 5.09 and 13.5 (KD?) respectively in Table IV. This protein has been identified by western blots of two - dimensional electrophoresis, using C.trachomatis proteins obtained from strain L2/343/Bu and chronically infected or convalescent patients sera. Further, the specification teaches spot number 12, N-terminal sequence TTESLETLVE (SEQ.ID.NO: 2) of L7/L12 protein However, The specification fails to teach L7/L12 protein, TTESLETLVE (SEQ.ID.NO: 2) has been shown either treating or preventing any Chlamydia infection. Further, the specification fails to teach homologue of ribosomal protein, L7/L12, homologue that has greater than 50%

identity to ribosomal protein, L7/L12, homologue that has greater than 90% identity to ribosomal protein, L7/L12 fragments of ribosomal protein L7/L12 with at least 7 amino acids. None of these broadly cited proteins and methods of treating or preventing Chlamydia infection using such proteins are not set forth in this specification. Therefore, the broadly claimed methods do not meet the written description provision of 35 U.S.C. 112, first paragraph. Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that (he or she] invented what is claimed." (See Vas-Cath at page 1116.).

The specification discloses L7/L12 protein from C.trachomatis, which is partially, characterized having predicted pI and molecular 5.09 and 13.5 (KD?) respectively, which corresponds to the protein spot 12 in Tables 2,3 and 4. Thus, an isolated *C.trachomatis* ribosomal protein L7/L12 (SEQ.ID.NO: 2) with predicted pI and molecular 5.09 and 13.5 respectively meets the written description provision of 35 U.S.C. 112, first paragraph for the reasons set forth below.

The specification fails to teach including homologue of ribosomal protein, L7/L12, homologue which has greater than 50% identity to ribosomal protein, L7/L12, homologue which has greater than 90% identity to ribosomal protein, L7/L12 fragments of ribosomal protein L7/L12 with at least 7 amino acids (examiner is viewing these proteins as variants) and it is noted that the claimed method of treatment or prevention of all Chlamydial infections using broadly claimed proteins do not exist as an invention. The actual biological function of *Chlamydia trachomatis* protein L7/L12 having predicted 5.09 pI and 13.5 KD molecular weight and its role in treating Chlamydial infection are not described adequately. The amount of

disclosure necessary to satisfy the written description requirement for utilizing the disclosed protein either in treating C.trachomatis infected individual or preventing the C.trachomatis infection is not well established. Further, none of the claimed variants have not been disclosed in such a way that one skilled in the art will be able to reasonable predict the outcome of the claimed methods. There is no written description support for a method of treating or preventing Chlamydial infection as claimed. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method. See Fiers v. Revel, 25 U5PQ2d 1601, 1606 (CAFC 1993) and Amgen Inc V Chugai Pharmaceutical Co Ltd., 18 U5PQ2d 1016. One cannot describe what one has not conceived. See Fiddes v. Baird, 30 U5PQ2d 1481, 1483. In Fiddes v. Baird, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class.

10. Claims 25-48 are also rejected under 35 U.5.C. 112, first paragraph, because the specification contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Instant claims are evaluated for enablement using Wands analysis. Many of the factors regarding undue experimentation have been summarized in In re Wands, 858 F.2d 731,8 USPQ2d 1400 (Fed.Circ.1988) as follows:

(1) the nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples, (6) the quantity of experimentation necessary, (7) the relative skill of those in the art, and (8) the breadth of the claims.

The nature of the invention is a method of treatment and a method of preventing Chlamydia infection comprising administering to a patient a therapeutic effective amount of ribosomal protein L7/L12.

It is noted that the specification fails to teach any and all ribosomal proteins could be used either for treating or for preventing *C.trachomatis* infection in a patient. The specification does not set forth by administering even C.trachomatis ribosomal protein L7/L12 (SEQ.ID.NO: 2) to a patient would be able to treat the infection. Further, homologue of ribosomal protein, L7/L12, homologue which has greater than 50% identity to ribosomal protein, L7/L12, homologue which has greater than 90% identity to ribosomal protein, L7/L12 fragments of ribosomal protein L7/L12 with at least 7 amino acids (examiner is considering them as variants) have been shown to induce a protective immune response so that this protein could be used in a method of treatment or prevention. The specification does not provide how would an artisan have used the protein and its variants to treat the infection against *C.trachomatis*. Furthermore, the patient's sera has not been shown to identify the claimed variants in an in vitro assay. The specifications does not ensure that the protein, L7//L12 or its variants would be able to successfully generate a protective immune response to treat or prevent an infection because the state of the art suggests that the protective immune response to infection with Chlamydia trachomatis is associated with antibody reactivity to species specific, serovar specific and serogroup specific determinants on the major outer membrane proteins (see Allen et al, Journal of Immunology 1991, 147; 674-679 and Batteiger et al 1996, Infection and Immunity , 64; 2839 - 2841). Therefore, the protective role of antibodies to ribosomal protein L7/L12 obtained from C.trachomatis is yet to be studied. Further, immune response generated by ribosomal protein, L7/L12 would be able to treat any and all Chlamydia infections as claimed are left for experimentation. Further, the specification provides no working examples demonstrating (i.e.,

guidance) enablement for any *in vivo method* of using the claimed protein or variants thereof. However, it is unclear whether this approach is feasible in the treatment of Chlamydial infections using the claimed protein because the target antigen, a ribosomal protein L7/L12, SEQ.ID.NO: 2 has not been shown to treat even an ongoing Chlamydia trachomatis infection. Thus, this method of treatment or prevention of Chlamydial infection using said ribosomal protein, L7/L12 or variants in the treatment of any and all Chlamydial infections (including infection caused by C.pneumoniae or C.trachomatis) must be considered highly unpredictable, requiring a specific demonstration of efficacy of the claimed protein, L7/L12 in treating specific Chlamydia infection. Absent such demonstration, the invention would require undue experimentation to practice the claimed invention. Therefore, it is concluded that the specification as filed is not enabling for the claimed invention as filed and an artisan would not have been able to practice the invention without undue experimentation.

Claim Rejections - 35 U.S. C. § 112, second paragraph

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

12. Claims 25-48 are rejected under 35 U.5.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 25 and 30 are vague in reciting "ribosomal protein L7/L12" It is not clear what are the metes and bounds of the ribosomal protein L7/L12? Does applicant intend to mean C.trachomatis ribosomal protein L7/L12 comprising the -terminal sequence TTESLETLVE SEQ.ID.NO: 2?

Claims 27, 30, 35, 39, 42 and 47 are vague for the recitation of "the protein has MW and pI characteristics of protein 12" because claims fail to satisfy the statute's requirement of adequately describing and setting forth the inventive concept. The inclusion of molecular weight, pI and additional structural parameters, such as amino acid sequence of the protein would enable more definitive identification of the claimed protein without ambiguity.

Claims 28, 36, 40 and 48 are vague for the recitation of " amino acid sequence disclosed in Table III on page 16" because claims fail to satisfy the statute's requirement of adequately describing and setting forth the inventive concept. The inclusion of specific amino acid sequence of the protein would enable more definitive identification of the claimed protein without ambiguity.

Claims 31and 43 are vague for the recitation of " at least 7 consecutive amino acids" because the claims 29 and 25 Or claims 41 and 37 do not contain any amino acid sequences that contain at least 7 consecutive amino acids.

Status of Claims

13. No claims are allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Padma Baskar whose telephone number is (703) 308-8886. The examiner can normally be reached on Monday through Friday from 6:30 AM to 4 PM EST

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Padma Baskar Ph.D

MARK NAVARRO
PRIMARY EXAMINER